

- abdominal (stomach) pain
- face becomes very round
- whitening or clouding of the lens (cataracts)
- slow healing of wounds
- existing infections can worsen
- patches of skin reddening
- signs of infection can be masked
- increased number of white blood cells
- risk of stroke is increased in Horton disease
- heart problems which can cause shortness of breath
- increased pressure in the eyeball (glaucoma)
- increased appetite which may result in weight gain
- carbohydrate imbalance in diabetes
- feeling of dependency on treatment
- high blood pressure (hypertension)
- increased cholesterol or fat levels in blood
- worsening of viral or fungal infections of the eye
- risk of contracting infection is increased
- muscle wasting of the upper arms and legs
- brittle bone disease or wasting of the bones
- hiding or altering reactions to skin tests such as for tuberculosis
- stomach ulcers with bleeding or perforation
- reduction of growth in babies, children and adolescents
- absence or irregularity of menstrual periods
- pressure on the nerve to the eye thinning of the tissues of the eye (sclera and cornea)
- raised pressure in brain (which can cause headaches, nausea and vomiting)
- ulcers in the gullet (oesophagus) which may cause periods discomfort on swallowing
- previous infections, such as tuberculosis (TB) may be re-activated (flare up).
- scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.
- a change in the levels of some hormones, mineral balance or protein in blood tests.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Prednisolone Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use these tablets after the expiry date shown on the pack after EXP. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Prednisolone Tablets contain

- The active ingredient is prednisolone.
- Each Prednisolone 2.5 mg Tablet contains 2.5 mg of prednisolone.
- Each Prednisolone 5 mg Tablet contains 5 mg of prednisolone.

- The tablets also contain lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, hypromellose, titanium dioxide (E171), triethyl citrate, sorbic acid, methacrylic acid ethyl acrylate copolymer, talc, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulfate, polyvinyl alcohol and macrogol 3350.
- Prednisolone 2.5 mg Tablets also contain black iron oxide (E172), red iron oxide (E172) and yellow iron oxide (E172)
- Prednisolone 5 mg Tablets also contain ponceau 4R red (E124), indigo carmine aluminium lake (E132) and sunset yellow FCF (E110).

##### What Prednisolone Tablets look like and contents of the pack

- Prednisolone 2.5 mg Tablets are dark brown, circular, deep biconvex, enteric coated tablets.
- Prednisolone 5 mg tablets are red, circular, deep biconvex, enteric coated tablets.
- Prednisolone Tablets are available in blister packs of 28 tablets.

##### Marketing authorisation holder and Manufacturer

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**Prednisolone 2.5 mg Gastro-Resistant Tablets;**  
**PL 17907/0553,**  
**Prednisolone 5 mg Gastro-Resistant Tablets;**  
**PL 17907/0554,**

**This leaflet was last revised in December 2021.**

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#### Package leaflet: Information for the user

### PREDNISOLONE 2.5 MG AND 5 MG GASTRO-RESISTANT TABLETS Prednisolone

- **Prednisolone is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor -you may need to reduce the dose gradually.
- **Prednisolone can cause side effects in some people** (read Section 4 Possible Side Effects below). Some problems such as mood changes (feeling depressed or 'high'), or stomach problems can happen straight away. If you feel unwell in anyway, keep taking your tablets, but see your doctor straight away.
- **Some side effects only happen after weeks or months.** These include weakness of arms and legs, developing a rounder face (read Section 4 Possible Side Effects for more information).
- **If you take it more than 3 weeks, you will get a blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.

**Now read the rest of this leaflet.** It includes other important information on the safe and effective use of this medicine that might be especially important for you.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Prednisolone Tablets are and what are they used for
2. What you need to know before you take Prednisolone Tablets
3. How to take Prednisolone Tablets
4. Possible side effects
5. How to store Prednisolone Tablets
6. Contents of the pack and other information

#### 1. What Prednisolone Tablets are and what are they used for

Prednisolone belongs to a group of medicines called steroids. Their full name is **corticosteroids**. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroids (such as prednisolone) is an effective way to treat various illnesses involving inflammation in the body. Prednisolone reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Prednisolone is used in a wide range of inflammatory and auto-immune conditions including:

- Allergies, including severe allergic reactions
- Inflammation affecting the:
  - Lungs, including asthma
  - Blood vessels and heart
  - Bowel or kidneys
  - Muscles and joints, including rheumatoid arthritis
  - Eye or nervous system
- Skin conditions
- Some infections
- Some cancers, including leukaemia, lymphoma and myeloma
- To prevent organ rejection after a transplant.

Also:

- To boost steroid levels when the body is not making enough natural steroid on its own
- To treat high calcium levels.

#### 2. What you need to know before you take Prednisolone Tablets

##### Check with your doctor first

- **If you have ever had severe depression or manic depression** (bipolar disorder). This includes having had depression before or while taking steroid medicines like prednisolone.
- **If any of your close family** has had these illnesses.

If either of these applies to you, **talk to a doctor before taking prednisolone.**

##### Do not take Prednisolone Tablets if you:

- Are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- Are suffering from a serious infection which is not being treated
- Are suffering from a herpes infection of the eye.
- Are suffering from galactose or lactose intolerance or glucose-galactose malabsorption.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone Tablets if you:

- Have Scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production. The doctor may advise that you have your blood pressure and urine regularly checked.

- Suffer from or have ever been treated for tuberculosis (TB)
  - Have high blood pressure
  - Have a heart condition
  - Have liver or kidney problems
  - Suffer from diabetes or diabetes runs in your family
  - Are going through, or are past the menopause
  - Have osteoporosis (thinning of the bone), particularly if you are past the menopause (the change of life)
  - Suffer from epilepsy (fits)
  - Suffer from stomach ulcers
  - Have taken Prednisolone (or other steroids) before and had muscular problems (steroid myopathy)
  - Are receiving treatment for a condition called myasthenia gravis (a rare muscle weakness disorder)
  - Have ever had blood clots, (for example, deep vein thrombosis [DVT], or thromboembolism)
  - Are planning to have a vaccination
  - Have Cushing's disease. (A hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating).
  - Suffer from hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
  - Have Duchenne's muscular dystrophy
  - Have inflammatory bowel disease such as Crohn's disease
  - Have an eye disease caused by fluid build-up at the back of the eye that causes visual impairment.
  - Experience blurred vision or other visual disturbances
  - Are undergoing immunosuppression therapy for example in the treatment of cancer
  - Suffer or have suffered from any mental illness
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

#### Children and adolescents

The use of steroids can slow down normal growth of children and adolescents. Your doctor may need to stop treatment or adjust the dose for your child accordingly. If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take this medicine.

#### Other medicines and Prednisolone Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Antivirals such as ritonavir or cobicistat which can be used to treat HIV infection
- Drugs for diabetes including insulin
- Antifungals such as ketoconazole and amphotericin which are used to treat fungal infections
- Ciclosporin which is used to treat rheumatic disease, skin complaints or after a transplant
- Antibiotics such as erythromycin and rifamycin which are used to treat bacterial infections
- Cardiac glycosides for example digoxin which is used to help strengthen a weak heart
- Antiepileptic drugs such as carbamazepine, phenobarbital, phenytoin and primidone which are used to treat epilepsy.
- Non-steroidal anti-inflammatory drugs (NSAIDs) for example aspirin, ibuprofen, and Indometacin used for pain relief or to treat rheumatic disease
- Mifepristone, used to induce labour or abortion

- Oestrogens, for example in the contraceptive pill or HRT
- Cytotoxic drugs for example methotrexate which is used to treat cancer
- Thiazide diuretics ("water tablets") for example bendro-flumethiazide used for water retention or high blood pressure
- Vaccinations: You must tell your doctor or nurse that you are taking a steroid before you are given any vaccinations. Steroids affect your immune response and you must not be given any live vaccines
- Medicines to treat high blood pressure
- Somatropin which is a growth hormone
- Anticoagulants for example warfarin which is used to thin the blood
- Acetazolamide which is used in the treatment of glaucoma and epilepsy
- Carbenoxolone which is used for ulcers
- Loop diuretics for example furosemide which is used to treat heart failure
- Salbutamol, formoterol, bambuterol, fenoterol, ritodrine, salmeterol and terbutaline used to treat asthma
- Theophylline which is used for asthma and chronic obstructive pulmonary disease (COPD)
- Antimuscarinics/ anticholinergics
- Immunosuppressants which dampen down the activity of the body's immune system
- Antithyroids such as carbimazole
- Antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion
- Isoniazid which is used to treat tuberculosis.

#### Prednisolone with food and drink

Prednisolone should be swallowed with water. You can take prednisolone before or after a meal. Avoid eating liquorice whilst taking prednisolone.

#### Pregnancy and breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are breast feeding you must tell your doctor before you start the treatment. Your doctor will want to examine your baby during your time of treatment. Small amounts of steroids are present in breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

#### Driving and using machines

If you feel dizzy or tired after taking prednisolone do not drive or operate machinery until these effects have worn off.

#### Important information about some of the ingredients of Prednisolone Tablets

This product contains lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicinal product.

Prednisolone 5 mg Tablets also contains sunset yellow FCF (E110) and ponceau 4R red (E124). This may cause allergic reactions.

#### Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

### 3. How to take Prednisolone Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor

or pharmacist if you are not sure.

#### Adults:

Different illnesses require different doses of Prednisolone. Depending on your illness your daily dose may be between 5 and 60 mg. In some cases you may be instructed to take it every other day. Your doctor will decide when and how to treat you with Prednisolone. Once your condition starts to get better, your doctor may also reduce your dosage before stopping treatment completely. This may depend on your illness, your dosage and how long you have been taking this medicine. In all cases you should be careful to follow any changes.

#### Elderly:

When steroids are taken by elderly patients some of the unwanted side effects can be more serious especially brittle bone disease, diabetes, high blood pressure, infections and thinning of the skin.

#### Children and adolescents:

The use of steroids can slow down normal growth of children and adolescents. In order to lessen this effect the tablets are often taken in a single dose every other day.

**Whilst you are taking Prednisolone, if any of the following occur tell your doctor straight away:**

- **Infections:** If you think you might have an infection. You are more likely to develop illness due to infection whilst you are taking Prednisolone. Also any existing infections may become worse. This is especially so during periods of stress. Certain infections can be serious if not controlled.
- **Chickenpox and Shingles:** If you, anyone in your family or regular contacts catches chickenpox or shingles. This is because you may become ill if you get chickenpox whilst taking Prednisolone. You should avoid contact with people who have chickenpox or shingles whilst taking Prednisolone and for up to 3 months after you stopped taking Prednisolone. Do not stop taking Prednisolone.
- **Measles:** If you, anyone in your family or regular contacts catches measles. You should avoid contact with people who have measles. Your doctor will give you a steroid treatment card. You must carry it with you at all times. You should show your steroid treatment card to anyone who is giving you treatment such as doctor, nurse or dentist.

#### Mental problems while taking prednisolone:

Mental health problems can happen while taking steroids like prednisolone (See also Section 4 'Possible side effects').

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

**If you take more Prednisolone Tablets than you should**

If you accidentally take too many Prednisolone tablets or someone else takes any of your medicine, you should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

#### If you forget to take Prednisolone Tablets

Do not worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose to make up for a forgotten dose. Then go on as before.

#### If you stop taking Prednisolone Tablets:

It is important to discuss your treatment with your doctor before stopping treatment. **Sudden stopping of treatment can cause the following symptoms:** fever, painful muscles and joints, inflammation of the eyes and nasal passages, painful and itchy skin lumps, loss of weight.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can have side effects, although not everybody gets them.

**Stop taking this medicine and contact your doctor straight away** if the following allergic reaction happens:

- Puffy, swollen face, tongue or body, which may cause shortness of breath, shock and collapse

#### Serious effects: tell a doctor straight away

- Inflammation of the pancreas (very severe abdominal pains)
  - Painful skin ulcers
- Steroids including prednisolone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like prednisolone.
- Feeling depressed, including thinking about suicide.
  - Feeling high (mania) or moods that go up and down.
  - Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.
  - Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.
  - worsening of schizophrenia

**If you notice any of these problems talk to a doctor straight away.**

**Not known (cannot be estimated from the available data):**

- |                             |                          |
|-----------------------------|--------------------------|
| • tiredness                 | • vision problems        |
| • blood clotting            | • nausea and vomiting    |
| • convulsion                |                          |
| • worsening of epilepsy     | • bruising               |
| • thinning of the skin      | • stretch marks          |
| • itching                   | • rash                   |
| • hives                     | • muscle pain            |
| • extra hair growth         | • bone fractures         |
| • tendon rupture            | • indigestion            |
| • acne                      | • bloating               |
| • weight gain               | • diarrhoea              |
| • depression                | • dizziness              |
| • euphoria (feeling high)   | • headache               |
| • vertigo (loss of balance) | • increased sweating     |
| • bulging eyes              | • sleeplessness          |
| • candidiasis (thrush)      | • general unwell feeling |
| • water salt retention      | • increased blood sugar  |
| • slow heart rate           |                          |